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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 98F-0797]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to expand the safe use of 5,7-bis(1,1 -dimethylethyl) -3-hydroxy-2(3H) -benzofuranone, reaction products with *o*-xylene as an antioxidant and/or stabilizer for propylene polymers and copolymers intended for use in contact with food. This action is in response to a petition filed by Ciba Specialty Chemicals Corp.

DATES: The regulation is effective (*insert date of publication in the Federal Register*). Submit written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (I-IFS-21 5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 24, 1998 (63 FR 5 1074), **FDA** announced that a food additive petition (FAP 8B4625) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591-9005. The

petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* [21 CFR 178.2010) to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food. Upon further review, FDA has determined that the petition proposed to expand the safe use of this additive for use in polypropylene polymers and copolymers only.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive as an antioxidant and/or stabilizer in olefin polymers intended for use in contact with food is safe, and (2) the additive will have the intended technical effect. Therefore, the regulations in § 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has ^{previously} ~~carefully~~ considered the potential environmental effects of this rule as announced in the notice of filing for the petition. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This **final** rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (insert date **30 days after date of publication in the Federal Register**), file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately

numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state, Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b), in the entry for 5,7-bis(1, 1-dimethylethyl)-3 -hydroxy-2(3H)-benzofuranone, reaction products with *o*-xylene by revising entry “2” under the headings “Substances” and “Limitations” to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
<p>* * *</p> <p>5,7-Bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with <i>o</i>-xylene (CAS Reg. No. 181314-46-7).</p>	<p>* * *</p> <p>For use only:</p> <p>2. At levels not to exceed 0.02 percent by weight of:</p> <p>(a) Propylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 3.1a, 3.2a, 3.2b, 3.4, or 3.5. The finished polymer may only be used in contact with food of types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter; or</p> <p>(b) Ethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, or 3.6 (where the density of each of these polymers is at least 0.94 gram per cubic centimeter), or 5. The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use 13 through H described in Table 2 of § 176.170(c) of this chapter; provided that the finished food-contact articles have a volume of at least 18.9 liters (5 gallons).</p>

Dated: 5/3/99

May 3, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

L. Robert Lake

L. Robert Lake
 Director
 Office of Policy, Planning and Strategic Initiatives
 Center for Food Safety and Applied Nutrition

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